IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE INNOCOLL HOLDINGS PUBLIC LTD. CO. SECURITIES LITIGATION	:	**CIVIL ACTION**
	:	**No. 17-341**

MEMORANDUM

PRATTER, J. MARCH 24, 2020

INTRODUCTION

How much information to investors, rather than mere guesswork, is enough when the issue is whether and how a federal government agency will evaluate a new pharmaceutical product? Hindsight and case law coalesce to create an ever increasing body of law that has done little to stem the tide of litigation arising from unrequited optimism. No formula has emerged and none will be proposed here.

In this securities class action, Plaintiffs allege that Innocoll Holdings Public Ltd. Co., Innocoll's Chief Executive Officer Anthony Zook, and Innocoll's Chief Medical Officer Dr. Lesley Russell made misleading statements or omissions about XaraColl, a collagen product the pharmaceutical company was developing during the class period. Even though Defendants supposedly knew, or recklessly failed to know, that XaraColl contained device components that had not yet been tested, they allegedly made positive statements about XaraColl's New Drug Application. Plaintiffs claim these statements allegedly failed to disclose the risk that the U.S. Food and Drug Administration (FDA) could reject the New Drug Application due to Innocoll's failure to treat XaraColl as a drug/device combination product. Plaintiffs contend that, by omitting such material information, Defendants misled investors who relied on the positive statements.

Plaintiffs invoke Section 10(b) of the Securities Exchange Act of 1934 and Rule 10b-5. They also make individual control liability claims against Mr. Zook and Dr. Russell under Section 20(a). Defendants first moved to dismiss the first amended complaint pursuant to Fed. R. Civ. P. 12(b)(6). Because Plaintiffs initially failed to meet the Private Securities Litigation Reform Act's (PSLRA) heightened pleading standard relating to the element of scienter, the Court granted the initial motion to dismiss with leave to amend. Plaintiffs then submitted a second amended complaint which added nearly 100 additional allegations. Defendants move to dismiss all the claims asserted in the second amended complaint under Rule 12(b)(6).

The second amended complaint meets the PSLRA's standards for pleading material misstatements or omissions and a strong inference of scienter. Because Defendants' boilerplate cautionary language accompanying their allegedly forward-looking statements to potential investors is unmeaningful, the PSLRA's "Safe Harbor" provision is inapplicable. As further outlined in this Memorandum, the Court therefore denies the motion to dismiss.

BACKGROUND

This securities class action purports to be brought on behalf of all persons who purchased or otherwise acquired publicly traded shares of Innocoll during a roughly two and one half year period between July 25, 2014 and December 29, 2016. Innocoll[1] is a pharmaceutical company based in Ireland with its U.S. headquarters in Newtown Square, Pennsylvania. Innocoll's common shares are traded on the NASDAQ. Innocoll develops and sells medical products based on its patented collagen technologies used in medical sponges, films, powders, and other structures. Plaintiffs allege that Innocoll has consistently operated at a loss in manufacturing and selling its

[1] At the start of the class period, Innocoll was Innocoll AG, a German company, but merged into Innocoll Holdings plc on March 16, 2016 and changed its domicile to Ireland. This merger apparently did not have a substantial effect on operations or ownership, and Innocoll Holdings plc is a successor in interest to Innocoll AG.

products. By March 2014, Innocoll had two major products in the pipeline: XaraColl (discussed in detail below) and Cogenzia, which is used for treating diabetic foot infections.

The individual defendants, Anthony Zook and Dr. Lesley Russell, were, respectively, Innocoll's Chief Executive Officer and Chief Medical Officer during the class period. Mr. Zook has over 30 years of experience in the pharmaceutical industry, including serving as President and CEO of AstraZeneca's North American division. Dr. Russell also has material experience developing pharmaceuticals from serving as Chief Operating Officer and Chief Medical Officer of TetraLogic Pharmaceuticals, Corp. from August 2013 through March 2016. Plaintiffs allege that the individual defendants each had an integral hand in making misleading statements to investors.

I. The FDA Approval Process

The FDA must approve drugs and devices before they can be sold in the United States. A sponsor is the person or company submitting an application for approval to the FDA. For purposes of this case, the FDA categorizes products as (i) drugs, (ii) devices, and (iii) combination products.

The FDA can, and will, provide guidance to sponsors on navigating the approval process. Although sponsors can request formal meetings to identify potential obstacles, sponsors are required to define specific areas where they need input, summarize the purpose of the meeting, submit a proposed agenda, and list questions for discussion. Sponsors are cautioned to also identify any professionals that should be in attendance, either by name or department. It is ultimately, however, the sponsor's responsibility to determine which category is the best fit for its product.

Drug Approval: Drugs are typically approved following three phases of clinical trials. Phase I establishes proper dosage and confirms that the drug is safe to be studied. Phase II

establishes clinical efficacy. During Phase III, the sponsor must submit a New Drug Application, which requires the sponsor to test the drug and submit evidence of safety and effectiveness. The FDA's Center for Drug Evaluation and Research then reviews the New Drug Application.

Device Approval: Although devices can follow a variety of paths to approval, a sponsor must generally demonstrate reasonable assurances of the device's safety and effectiveness. The Center for Devices and Radiological Health reviews device applications.

Drug/Device Combination Approval: Products with both drug and device components are called drug/device combinations. These products require approval of both the drug and the device elements. The FDA created the Office of Combination Products to develop guidance and regulations governing combination products, to assign an FDA center to have primary jurisdiction over combination products, and to ensure timely and effective premarket review of combination products. Reportedly, around 300 combination product applications are filed annually.

II. XaraColl

One of Innocoll's products is XaraColl, which provides sustained postsurgical pain relief. XaraColl is a collagen product that treats postoperative pain with bupivacaine. In layman's terms, XaraColl is a collagen matrix that is implanted at, and gradually releases pain medicine directly to, the surgical site. In doing so, it reduces the need for post-surgery opioids and the risks associated with them. XaraColl is absorbed by the patient's body and does not need to be removed later. XaraColl's patent, filed in 2008, refers to XaraColl as a "drug delivery device" and a "device comprising a fibrillar collagen matrix." Sec. Am. Compl. at ¶ 59.

Innocoll met with representatives of the FDA twice to discuss XaraColl. The first meeting occurred at the end of Phase II to discuss XaraColl's Phase III trials. The second meeting was a

formal meeting about Phase III trials. At these meetings, Innocoll only discussed filing XaraColl as a drug and never asked the FDA whether XaraColl should be filed as a drug/device combination.

A Medical Affairs Consultant (MAC) employed at Innocoll from July 2015 until November 2015 has claimed that XaraColl had device components. The MAC ensured that the promotional materials were medically and technically accurate and reported directly to then-Chief Medical Officer, Dr. James Tursi. He also worked closely with David Prior, who has been in senior positions at Innocoll since 2004. The MAC, apparently acting as a confidential witness for Plaintiffs in this case, says that Mr. Prior and Dr. Tursi both told him that XaraColl would be considered a device in the U.S. *Id.* at ¶ 95.

On May 25, 2016, Innocoll announced that XaraColl was all but ready for New Drug Application filing and the stock prices rose from $7.11/share to $10.51/share. And, on November 3, 2016, Innocoll announced that it was submitting XaraColl's New Drug Application. That same day, the company announced it was abandoning its other major drug, Cogenzia, because the drug failed Phase III trials.

Innocoll submitted the New Drug Application for XaraColl as a drug and not a drug/device combination.

III. FDA's "Refusal to File" Letter

On December 29, 2016, Innocoll released a statement that the FDA issued a "refusal to file" letter for XaraColl. A "refusal to file" letter means that the FDA will not conduct a substantive review of the application extant because it is incomplete. The FDA determined that XaraColl should be characterized as a drug/device combination, which required Innocoll to submit additional information about the device components. Innocoll planned to work with the FDA to "define a path forward for a successful re-filing of [the] application at the earliest point in time."

Id. at ¶ 149. On December 30, 2016, Innocoll's shares fell $1.08 per share and closed at $0.69 per share.

IV. Allegedly Misleading Statements and/or Omissions

The second amended complaint outlines a number of Defendants' allegedly misleading statements or omissions, particularly concerning the two formal meetings Innocoll had with the FDA. The second amended complaint alleges the same misleading statements that were included in the first amended complaint. Those statements fall within five categories: (1) statements about the end-of-phase-II meeting with the FDA; (2) statements about the July 2015 meeting with the FDA and phase III study; (3) statements on earnings calls about goals and expectations; (4) answers to questions about non-clinical progress; and (5) statements about expectations and approval of XaraColl's New Drug Application.

Shareholders allege that Innocoll, through Mr. Zook and Dr. Russell, made positive public statements about the FDA likely approving XaraColl's New Drug Application but did not disclose the risk that XaraColl may require additional device trials and approval. These statements allegedly led investors to believe that Innocoll had raised all potential red flags with the FDA, no non-clinical obstacles remained, the New Drug Application was on schedule, and the FDA was likely to approve XaraColl.

Plaintiffs allege that Innocoll and its senior people were always aware, or at least should have been aware, that the collagen matrix component of XaraColl was a device and would need to be tested separately to secure approval. Innocoll never asked the FDA if it should test XaraColl as a drug/device combination product, so, according to plaintiffs, the statements misled investors into believing that the FDA was progressing toward a fully informed opinion when the agency was actually missing key information about XaraColl. Essentially, Plaintiffs contend that Defendants

made all of these statements to entice investors, knowing full well or ignoring the fact that the FDA would not approve XaraColl because the company had not tested the product's device components. Ultimately, the FDA refused to consider the XaraColl application for that reason.

Defendants claim that all of the statements were factually true and that the company was not aware that XaraColl needed to be filed as a drug/device combination product. Instead, Defendants argue that they simply made an unintended and expensive mistake in believing that XaraColl should have been tested and filed as a drug in its New Drug Application.

A. Statements about the End-of-Phase-II Meeting with the FDA

Innocoll released three statements that referenced the end-of-Phase-II meeting: the IPO registration statement, the 2014 20-F report, and the F-1 registration statement. *Id.* at ¶¶ 99, 106, 110. In these statements, Innocoll stated that the FDA agreed to Innocoll's approach for XaraColl's Phase III trials. For example, the IPO registration statement stated in part: "Following our end-of-Phase II meeting, *the FDA agreed* to permit us to pursue such integrated end point in our Phase III trial." *Id.* at ¶ 99 (emphasis added). And the F-1 registration statement said: "The primary endpoint in our two planned Phase III trials will use this integrated Silverman method assessment of pain and opioid consumption, *as agreed to with the FDA* in our end-of-Phase-II meeting." *Id.* at ¶ 110 (emphasis added).

B. Statements about the July 2015 Meeting with the FDA and Phase III Study

Innocoll made a number of statements about the company's July 2015 Meeting with the FDA, in which the FDA allegedly approved XaraColl's proposed Phase III study. Those statements were made in the 2015 20-F, amendment to the registration statement, and the June 2016 preliminary prospectus supplement. *Id.* at ¶¶ 116-118, 124, 130. The 2015 20-F stated that

the company received guidance from the FDA, the FDA reviewed data from XaraColl's Phase II study, and the FDA "agreed" with and "approved" the Phase III study protocol. *Id.* at ¶¶ 116-118.

C. Statements on Earnings Calls about Goals and Expectations

Plaintiffs next point to statements Innocoll made on the earnings calls in 2015 about goals and expectations for the company. During those calls, Mr. Zook stated that Innocoll planned to "focus on achieving all [their] clinical milestones" and that meeting their "key delivery dates" was their "highest priority." *Id.* at ¶¶ 181-183.

D. Answers to Questions about Non-Clinical Progress

During two conference calls, Mr. Zook and Dr. Russell answered questions about whether there were any non-clinical issues that needed to be solved before Innocoll could file XaraColl's New Drug Application and safety database. *Id.* at ¶¶ 120, 127. On both calls, Defendants answered in the negative. *Id.*

E. Statements about Expectations and Approval of XaraColl's New Drug Application

The last group of statements Plaintiffs highlight concern the expectations and likelihood of approval of XaraColl's New Drug Application. *Id.* at ¶¶ 124, 126, 133, 140, 142, 144, 145. In an amendment to the registration statement, Innocoll stated: "The FDA deemed our single-dose approach acceptable in our recent Type C meeting . . . . We expect to submit a[] [New Drug Application] for XaraColl at the beginning of the fourth quarter of 2016." *Id.* at ¶ 124. A press release from May 25, 2016 repeated that "Data supports on-schedule [New Drug Application] filing this year." *Id.* at ¶ 126. A June 13, 2016 preliminary prospectus supplement "anticipated approval of [XaraColl's New Drug Application]." *Id.* at ¶ 133. On a November 2016 conference call, Dr. Russell reiterated that she did not think approval was in question. *Id.* at ¶ 140.

F. Defendants' Alleged Motivations to Make Misleading Statements

Plaintiffs plead a few different motivations Defendants allegedly had for making their misleading statements and omissions. Plaintiffs contend that Innocoll was operating "on the razor's edge" and needed cash to complete its FDA trials for XaraColl and Cogenzia, which it did by selling its shares after announcing their positive statements. *Id.* at ¶ 166. The company allegedly was not able to generate enough interest and had to paint a rosier picture of XaraColl's purportedly imminent FDA approval to inflate stock prices. For example, Plaintiffs allege that just weeks after Defendants announced that "approval was all but guaranteed" after conducting their Phase III clinical trials, Innocoll sold $40 million of its shares in an attempt to keep the company afloat. *Id.* at ¶ 11. Plaintiffs also allege that Innocoll was so strapped for cash that, as a means to save $10 million, they decided to forego the pharmacokinetic and other non-clinical studies needed to establish the collagen sponge's safety and effectiveness.

Meanwhile Innocoll was also attempting to find a buyer, either for the company itself or the rights to XaraColl. Innocoll approached about 50 potential buyers about purchasing the company, licensing or acquiring XaraColl's European rights, and licensing or acquiring XaraColl's U.S. rights. Plaintiffs believe that Innocoll misled investors about the likelihood of XaraColl's FDA approval because Innocoll was contemporaneously seeking to monetize it. After ongoing negotiations, Gurnet Point offered to acquire Innocoll for $9.50/share in cash. Innocoll's Board rejected this offer but continued negotiations with Gurnet Point. Mr. Zook allegedly stood to make $5.5 million if the offer went through and he sold his shares.

Moreover, Plaintiffs contend that Mr. Zook and Dr. Russell had career motivations to overstate the likelihood of XaraColl's FDA approval. For example, Mr. Zook promised that Innocoll would reach four targets within a 12-month time frame ending in March 2016 and claimed

that Innocoll had enough cash to take XaraColl and Cogenzia through their trials. *Id.* at ¶¶ 182, 183. Plaintiffs say that Mr. Zook was motivated financially and professionally to live up to these promises that he ultimately could not keep. As for Dr. Russell, Plaintiffs plead that after coming to Innocoll from a failed pharmaceutical company, she feared that she would lose her job if she told investors that Innocoll needed more cash. *Id.* at ¶ 196.

PROCEDURAL HISTORY

Defendants filed a motion to dismiss the first amended complaint under Fed. R. Civ. P. 12(b)(6), arguing that Plaintiffs failed to state Section 10(b) and Rule 10b-5 claims and plead control person liability under Section 20(a). Because Defendants' first motion to dismiss included a declaration from the confidential witness quoted in Plaintiffs' first amended complaint, Plaintiffs filed a motion under Rule 12(d) to convert the motion to dismiss into one for summary judgment. After oral argument, the Court denied Plaintiffs' Rule 12(d) motion and granted Defendants' motion to dismiss with leave to amend. The Court ultimately concluded that Plaintiffs "did not quite" meet the PSLRA's heightened pleading standard for scienter. Mem. at 11 (Doc. No. 46).

In granting the motion to dismiss, the Court rejected Plaintiffs' reliance on generalized allegations from the confidential witness that non-defendants knew of XaraColl's device components. Moreover, Plaintiffs cited Innocoll's decade's worth of experience working with collagen and bringing eight other collagen products to market without adequately explaining the similarities between XaraColl and Innocoll's other collagen technologies. The Court also acknowledged that Plaintiffs pleaded only generalized allegations that Innocoll was motivated to mislead investors because it was underfunded. Finally, the Court found that the fact that XaraColl's patent itself refers to XaraColl as a drug delivery device "is certainly an arrow in the plaintiffs' quiver." *Id.* at 18. However, because the patent language was "not enough in and of

itself to survive a motion to dismiss under the PSLRA's heightened pleading standard," the first amended complaint was dismissed with leave to amend. *Id.* at 18-19.

Plaintiffs then filed their second amended complaint. The nearly 100 new paragraphs added to the second amended complaint primarily concern the patents for XaraColl and its collagen sponge, CollaRx, an FDA guidance document and database that Plaintiffs contend should have made it clear to Defendants to treat XaraColl as a drug/device combination product. The new pleading also includes various additional motive allegations. Defendants again move to dismiss the second amended complaint. The Court heard oral argument on the motion to dismiss.

LEGAL STANDARD

A Rule 12(b)(6) motion to dismiss tests the sufficiency of a complaint. To survive a motion to dismiss, the plaintiff must plead "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

In evaluating the sufficiency of a complaint, the Court adheres to certain well-recognized parameters. For one, the Court "must consider only those facts alleged in the complaint and accept all of the allegations as true." *ALA, Inc. v. CCAIR, Inc.*, 29 F.3d 855, 859 (3d Cir. 1994). Also, the Court must accept as true all reasonable inferences emanating from the allegations and view those facts and inferences in the light most favorable to the nonmoving party. *See Revell v. Port Auth of N.Y. & N.J.*, 598 F.3d 128, 134 (3d Cir. 2010). If a claim "is vulnerable to 12(b)(6) dismissal, a district court must permit a curative amendment, unless an amendment would be inequitable or futile." *Phillips v. Cty. of Allegheny*, 515 F.3d 224, 236 (3d Cir. 2008).

Congress enacted the PSLRA as a "check against abusive litigation by private parties" levied at "companies and individuals whose conduct conforms to the law." *Tellabs*, 551 U.S. at

313. The PSLRA imposes "exacting pleading requirements" that oblige "plaintiffs to state with particularity both the facts constituting the alleged violation, and the facts evidencing scienter, *i.e.*, the defendant's intention 'to deceive, manipulate, or defraud.'" *Id.*; *see also OFI Asset Mgmt. v. Cooper Tire & Rubber*, 834 F.3d 481, 490 (3d Cir. 2016) (quoting *Institutional Inv'rs Grp. v. Avaya, Inc.*, 564 F.3d 242, 252 (3d Cir. 2009)) ("[I]n cases alleging securities fraud, plaintiffs must 'satisfy the heightened pleading rules codified in' the PSLRA.").

"In analyzing a motion to dismiss under the PSLRA, [a] [c]ourt must examine the complaint in its entirety, as well as documents incorporated into the complaint by reference or matters of which a court may take judicial notice." *In re NutriSystem, Inc. Sec. Litig.*, 653 F. Supp. 2d 563, 566 n.2 (E.D. Pa. 2009) (citing *Tellabs v. Makor Issues & Rights, Ltd.*, 551 U.S. 308 (2007); *Winer Family Trust v. Queen*, 503 F.3d 319, 327 (3d Cir. 2007)).

DISCUSSION

Under Section 10(b) of the Securities Exchange Act, it is unlawful for a person to "use or employ, in connection with the purchase or sale of any security . . . any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe as necessary or appropriate in the public interest or for the protection of investors." 15 U.S.C. § 78j(b). To state a Rule 10b-5 claim for securities fraud, Plaintiffs must "allege [that] defendants made a misstatement or an omission of material fact with scienter in connection with the purchase or the sale of a security upon which plaintiffs reasonably relied and plaintiff[s'] reliance was the proximate cause of their injury."[2] *Winer Family Trust*, 503 F.3d at 326; 17 C.F.R § 240.10b-5(b)). Liability for the statements made by Mr. Zook and Dr. Russell, "if they were

[2] Defendants do not contend that Plaintiffs failed to adequately plead that their reliance on Defendants' alleged misstatements caused them injury. Accordingly, the Court does not focus on this element of Plaintiffs' *prima facie* case.

fraudulent, can also be imputed to [Innocoll] because '[a] corporation is liable for statements by employees who have apparent authority to make them.'" *Avaya, Inc.*, 564 F.3d at 251-52 (quoting *Makor Issues & Rights, Ltd. v. Tellabs, Inc.*, 513 F.3d 702, 708 (7th Cir. 2008)).

As they did in response to the first amended complaint, Defendants move to dismiss the second amended complaint because allegedly failed to adequately plead Section 10(b) and Rule 10b-5 claims and, thus, have also failed to plead control person liability. Defendants argue that the second amended complaint fails to state Section 10(B) and Rule 10b-5 claims because (1) Plaintiffs fail to adequately plead scienter; (2) Plaintiffs fail to plead actionable, material misleading statements or omissions; and (3) Innocoll's forward-looking statements are protected by the PSLRA's "Safe Harbor" provision.

I. Scienter

Defendants contend that Plaintiffs failed to plead a "strong inference" of scienter in their second amended complaint. The Court disagrees.

A. Scienter Pleading Requirements under the PSLRA

The PSLRA "requires the plaintiffs, with respect to each act or omission, to state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." *GSC Partners CDO Fund v. Washington*, 368 F.3d 228, 237 (3d Cir. 2004) (internal quotations omitted); 15 U.S.C. § 78u-4(b)(2)(A). Furthermore, under section "78u-4(b)(2), 'a plaintiff can no longer plead the requisite scienter element generally, as he previously could under [Fed. R. Civ. P.] 9(b).'" *Avaya, Inc.*, 564 F.3d at 253 (quoting *Mizzaro v. Home Depot, Inc.*, 544 F.3d 1230, 1238 (11th Cir. 2008)); *see also id.* ("The PSLRA's requirement for pleading scienter . . . marks a sharp break with Rule 9(b)."). "The plaintiffs may establish a 'strong inference' that the defendants acted with 'scienter' 'either (a) by alleging facts to show that defendants had both

motive and opportunity to commit fraud, or (b) by alleging facts that constitute strong circumstantial evidence of conscious misbehavior or recklessness.'" *Id.* (quoting *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1418 (3d Cir. 1997)).

Motive must be plead with particularity and give rise to a strong inference of scienter. *GSC Partners*, 368 F.3d at 237. To infer scienter from a defendant's motive and opportunity, "the plaintiff should demonstrate a logical connection between the alleged fraud and motive in order to establish a reasonable inference of fraud." *In re Intelligroup Sec. Litig.*, 527 F. Supp. 2d 262, 283-84 (D.N.J. 2007). "Blanket assertions of motive and opportunity" do not suffice, and "catch-all allegations that defendants stood to benefit from wrongdoing and had the opportunity to implement a fraudulent scheme are no longer sufficient, because they do not state facts with particularity or give rise to a strong inference of scienter." *In re Advanta Corp. Sec. Litig.*, 180 F.3d 525, 535 (3d Cir. 1999). In addition, "[m]otives that are generally possessed by most corporate directors and officers do not suffice; instead, plaintiffs must assert a concrete and personal benefit to the individual defendants resulting from this fraud." *GSC Partners*, 368 F.3d at 237 (quoting *Kalnit v. Eichler*, 264 F.3d 131, 139 (2d Cir. 2001)). "Though it is not necessary to plead motive to establish that a defendant acted with scienter, its presence can be persuasive when conducting a holistic review of the evidence." *Rahman v. Kid Brands, Inc.*, 736 F.3d 237, 245 (3d Cir. 2013) (citing *Tellabs*, 551 U.S. at 325-26).

"Where motive is not apparent, it is still possible to plead scienter by identifying circumstances indicating conscious behavior by the defendant, though the strength of the circumstantial allegations must be correspondingly greater." *Glaser v. The9, Ltd.*, 772 F. Supp. 2d 573, 587 (S.D.N.Y. 2011). "A reckless statement is one involving not merely simple, or even inexcusable negligence, but an extreme departure from the standards of ordinary care, and which

presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it." *Avaya, Inc.*, 564 F.3d at 267 n. 42 (internal citation and quotation marks omitted). "This looks like two criteria—knowledge of the risk and how big the risk is—but as a practical matter it is only one because knowledge is inferable from gravity ('the danger was either known to the defendant or so obvious that the defendant must have been aware of it')." *Makor*, 513 F.3d at 704.

"When the facts known to a person place him on notice of a risk, he cannot ignore the facts and plead ignorance of the risk." *Avaya, Inc.*, 564 F.3d at 270 (quoting *Makor*, 513 F.3d at 704). Indeed, courts have described recklessness to "encompass[,] 'at a minimum[,] . . . willful blindness.'" *Benjamin v. Kim*, No. 95-9597, 1999 WL 249706, at *8 (S.D.N.Y. Apr. 28, 1999) (quoting *In re Kidder Peabody Sec. Litig.*, 10 F. Supp. 2d 398, 415 (S.D.N.Y. 1998)); *see Chill v. General Elec. Co.*, 101 F.3d 263, 269 (2d Cir. 1996) ("'An egregious refusal to see the obvious, or to investigate the doubtful, may in some cases give rise to an inference of . . . recklessness.'"); *In re Fischback Corp. Sec. Litig.*, No. 89-5826, 1992 WL 8715, at *6 (S.D.N.Y. Jan. 15, 1992) ("[R]eckless disregard of the truth satisfies the scienter requirements of § 10(b) when the defendant deliberately failed to acquire the information that would have indicated to her that her statements were false or misleading.").

A plaintiff must "specifically allege facts constituting strong circumstantial evidence that 'defendants knew, or, more importantly, should have known that they were misrepresenting material facts related to the corporation.'" *Hall v. Johnson & Johnson*, No. 18-1833, 2019 WL 7207491, at *20 (D.N.J. Dec. 27, 2019) (quoting *In re Campbell Soup Co. Sec. Litig.*, 145 F. Supp. 2d 574, 599 (D.N.J. 2001)). A plaintiff relying on a recklessness theory must specifically allege "defendants' knowledge of facts or access to information contradicting their public statements."

In re Campbell Soup, 145 F. Supp. 2d at 599 (quoting *Novak v. Kasaks*, 216 F.3d 300, 308 (2d Cir. 2000)). In doing so, a plaintiff "'must specifically identify the reports or statements that are contradictory to the statements made,' or must 'provide specific instances in which Defendants received information that was contrary to their public declarations." *Glaser*, 772 F. Supp. 2d at 588; *see In re Intelligroup*, 527 F. Supp. 2d at 286 ("'[W]here plaintiffs contend defendants had access to contrary facts, they must specifically identify the reports or statements containing this information.'") (citing *Novak*, 216 F.3d at 309).

To support a strong inference of scienter, "[a] complaint will survive . . . only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Tellabs*, 551 U.S. at 324. Thus, under the PSLRA, courts must "weigh the 'plausible, nonculpable explanations for the defendant's conduct' against the 'inferences favoring the plaintiff.'" *Avaya, Inc.*, 564 F.3d at 267 (quoting *Tellabs*, 551 U.S. at 324). "The inference that the defendant acted with scienter need not be irrefutable, *i.e.*, of the smoking-gun genre, or even the most plausible of competing inferences." *Tellabs*, 551 U.S. at 324 (internal quotation marks omitted). "The pertinent question is 'whether all of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard.'" *Avaya, Inc.*, 564 F.3d at 267 (quoting *Tellabs*, 551 U.S. at 323): *see also Tellabs*, 551 U.S. at 326 ("We reiterate, however, that the court's job is not to scrutinize each allegation in isolation but to assess all the allegations holistically.").

The Third Circuit Court of Appeals has "explicitly approved of scienter analyses that assess individual categories of scienter allegations individually when it is clear, as it is here, that a district court ultimately considered the allegations as a whole." *In re Hertz Global Holdings, Inc.*, 905

F.3d 106, 115 (3d Cir. 2018) (citing *OFI Asset Mgmt.*, 834 F.3d at 493) (noting that simply because a court is "thorough in explaining why it found scienter lacking as to each asserted misrepresentation does not suggest that it did not consider the allegations as a whole"). For the sake of thoroughness, the Court will, therefore, comment on the individual allegations bearing on scienter before assessing whether the pleadings holistically give rise to a strong inference of scienter.

B. Evidence of Scienter

Plaintiffs argue that their second amended complaint states with particularity facts supporting an inference that Defendants misled investors into believing that the FDA's approval of XaraColl's New Drug Application was all but guaranteed, when, in fact, Defendants knew or should have known that additional device trials and approval were necessary. In doing so, Plaintiffs point to the following evidence: (1) a statement from the Medical Affair Consultant (MAC); (2) Innocoll's (corporate and executives') experience with collagen products; (3) the Intercenter Agreement and inactive ingredients database posted on the FDA's website; (4) the XaraColl and CollaRx patents; and (5) Defendants' alleged motives, including a desire to raise money for the FDA trials and to keep Innocoll alive, achieve a higher price point from Gurnet Point, and Mr. Zook's and Dr. Russell's personal career motivations.

The second amended complaint's pleadings regarding the MAC's statement and Innocoll's general experience with collagen products are nearly identical to the pleadings set forth in the first amended complaint. Accordingly, the Court maintains the observations articulated in the memorandum dismissing the first amended complaint regarding Plaintiffs' first two pieces of evidence if they amounted to the sum and substance of the allegations alone. Mem. at 14-18. This Memorandum now focuses on the remaining pieces of evidence.

1. Motive and Opportunity Allegations

Plaintiffs allege that Defendants were motivated to mislead investors because Innocoll was essentially on the ropes financially and needed more money to fund its drug development costs. So, the allegations go, Innocoll sought to achieve a higher offer from its prospective buyer, Gurnet Point—a transaction that could have resulted in rescuing Innocoll itself and, in the wake of that rescue, Mr. Zook making a $5.5 million profit while enhancing the personal career motivations of Mr. Zook and Dr. Russell.

a. Innocoll's Underfunding for its Drug Development Costs

The first amended complaint generally alleged that Innocoll sought to secure financing to assure the company's continued survival. Although the Court ultimately dismissed the first amended complaint for failing to allege scienter, it acknowledged that "[t]he fact that Innocoll was generally underfunded may provide some evidence of a motive for Innocoll executives to hide any flaws in XaraColl's [New Drug Application.]" Mem. at 19 (Doc. No. 46).

In the second amended complaint, Plaintiffs allege that Innocoll was desperately in need of more cash in order to fund its drug development expenses. According to Innocoll's 2015 20-F report, Innocoll's ability to survive was contingent upon its ability to raise funds for expensive clinical trial programs. Sec. Am. Compl. at ¶ 155. In Innocoll's Q1 2015 earnings call, Mr. Zook estimated that Innocoll's Phase III trials would cost $50 million. *Id.* at ¶ 154. Between March 31, 2014 and December 31, 2016, however, Innocoll allegedly spent approximately $100 million more than it earned. *Id.* Plaintiffs also allege that Defendants intentionally skipped conducting XaraColl's necessary $10 million device trials to reduce their development costs. *Id.* at ¶ 8. Plaintiffs' narrative poses that even after saving this $10 million, Defendants still needed to raise substantial funds to pay for the drug trials that they did run.

Because Innocoll could only obtain debt financing at high rates, Plaintiffs contend that Innocoll decided to announce misleading positive results to raise money from the equity market. For instance, Plaintiffs allege that just weeks after Defendants announced that "approval was all but guaranteed" after conducting positive Phase III clinical trials, Innocoll sold $40 million of its shares. *Id.* at ¶ 11; Oral Argument Tr. 26:16-27:1. Defendants argue that the financial statements in Innocoll's SEC filings show that the company had plentiful funds during the relevant time period, usually somewhere between $22 and $54 million dollars. Plaintiffs suggest that Defendants are inviting the Court to inappropriately infer that Innocoll's balance sheets showed merely surplus, unallocated cash. *See Revell*, 598 F.3d at 134 (noting that a court must accept as true all reasonable inference emanating from the allegations and view those facts and inference in the light most favorable to the nonmoving party). Even so, Innocoll admitted that the company failed to meet its funding goals. Sec. Am. Compl. at ¶¶ 5, 159a, b.

b. Innocoll's Negotiations with Gurnet Point

After ongoing communications with Innocoll, Gurnet Point offered to acquire Innocoll at $9.50/share. Despite the Board's eventual rejection of Gurnet Point's offer, Plaintiffs claim that Innocoll had an incentive to keep its valuation artificially high as a means to increase Gurnet Point's price point. In particular, on a personal note Mr. Zook individually stood to get more than $5.5 million for his 586,563 shares as a result of the hoped for buyout. Pl.s' Ex. 1 at 24 (Doc. No. 53-1).

Defendants argue that this alleged motive is insufficient to support a strong inference of scienter because it is one "generally possessed by most corporate directors and officers." *GSC Partners*, 368 F.3d at 237; Oral Argument Tr. 48:5-11. This defense argument would dismiss any consideration of financial greed, a general, recognized human motivator, in any case merely

because it is indeed a common condition. The Court declines to accept such an ironic argument. After all, scienter may be inferred from a variation of the motivation by greed "when defendants[] were motivated to inflate company stock prices as a means to effectuate a specific acquiring that would not otherwise be possible without fraudulently inflating stock prices." *In re Vivendi Universal*, S.A., 381 F. Supp. 2d 158, 185 (S.D.N.Y. 2003); *see In re SLM Corp. Sec. Litig.*, 740 F. Supp. 2d 542, 557-58 (S.D.N.Y. 2010) (finding a plaintiff's motive allegations regarding a merger to "transcend a generic corporate desire to negotiate favorable terms" where the complaint alleged a "concrete and personal benefit" of the individual defendant); *Glidepath Holding B.V. v. Spherion Corp.*, 590 F. Supp. 2d 435, 455 (S.D.N.Y. 2007) (noting that complaints containing "allegations that one party to a sale had a financial incentive to 'paint a far rosier financial picture than actually existed in order to induce' the other party into a sale, such allegations [are] sufficient to survive Rule 9(b)") (quoting *Cohen v. Koenig*, 25 F.3d 1168, 1174 (2d Cir. 1994)).

Defendants also argue that Mr. Zook and Dr. Russell had no incentive to deceive Gurnet Point because the officers sought to work for Gurnet Point in the future. Presumably, this argument goes: why would they mislead the very entity for which they expected to soon be working? Furthermore, Defendants infer that Gurnet Point must have been a sophisticated company that would surely have discovered the problems XaraColl faced after performing extensive due diligence, thus rendering efforts by Mr. Zook and Dr. Russell to mislead Gurnet Point meaningless. However, the second amended complaint contains no such allegations concerning the officers' alleged desire to work at Gurnet Point, Gurnet Point's sophistication, or the due diligence Gurnet Point allegedly conducted before making an offer to acquire XaraColl. Proof of such circumstances will, no doubt, await development of the record, thus very likely providing the Court with an appropriate time to consider the import of such circumstances.

c. Mr. Zook's and Dr. Russell's Career Motivations

Plaintiffs allege that Mr. Zook and Dr. Russell declared misleading statements to save or bolster their careers. Plaintiffs assert that Mr. Zook wanted to live up to promises he ultimately could not keep in order to meet various targets for regulatory and clinical milestones and budgeting goals concerning the development of XaraColl and Cogenzia. Plaintiffs contend that Dr. Russell feared that, after coming from a failed pharmaceutical company, she might well lose her job if she told investors that Innocoll needed more cash. Courts have found that an executive's motive to live up to promises or an executive's realistic fears that his or her career is at stake can support a particularized motive supporting scienter. *See, e.g.*, *In re Telxon Corp. Sec. Litig.*, 133 F. Supp. 2d 1010, 1032 n. 5 (N.D. Ohio 2000) (finding new CEO's motive "to manipulate revenue in order to live up to their own promises" supported an inference of scienter); *In re Cabletron Sys., Inc.*, 311 F.3d 11, 39 (1st Cir. 2002) (finding motive allegations adequate where disclosure of fact may imperil career).

2. XaraColl Patent

In spite of having dismissed the first amended complaint, the Court acknowledged in doing so that "the patent's own language is certainly an arrow in the plaintiff's quiver." Mem. at 18 (Doc. No. 46). Notably, Innocoll titled XaraColl's U.S. patent application as "[a] drug delivery device for providing local analgesia, local anesthesia or nerve blockage." Sec. Am. Compl. at ¶ 59. In fact, the patent refers to XaraColl as a drug delivery device a total of 47 times. *Id.* In their second amended complaint, Plaintiffs added facts supporting the inference that Mr. Zook had significant personal knowledge of the patent's actual operative language. Specifically, the second amended complaint alleges that Mr. Zook (1) sought to reissue the XaraColl patent; (2) announced Innocoll's intentions to reissue the patent; and (3) discussed the patent during phone calls with

investors on response. In response Innocoll argues that Plaintiffs' amended pleadings demonstrate only that Mr. Zook was generally aware of the patent, not that he thoroughly read or relied on the patent's language. The reasons for choice of language must await proper documentation in the record before the Court can base a ruling on it.

Defendants posit that the patent included the "drug delivery device" language not to follow the FDA's lingo, but rather to mirror language apparently used in their patent pursued in Ireland to ensure priority in both countries. As Plaintiffs appropriately point out, the Irish patent is not mentioned in the second amended complaint, nor is it in any way essential to understanding their allegations. Although at the Rule 12(b)(6) stage the Court may take judicial notice that the Irish patent was filed, it abstains from taking judicial notice of Defendants' explanation that the U.S. patent was filed with the "drug delivery device" language solely as a means to mimic the language used in the Irish patent.

3. CollaRx Patent

The second amended complaint also asserts that the patent application for XaraColl's collagen sponge, CollaRx, further demonstrates that Defendants should have known to treat XaraColl as a drug/device combination. The CollaRx patent acknowledged that "[m]any of today's products aimed at localized [sic] delivery are device-drug combinations." *Id.* at ¶ 76. As stated in CollaRx's patent application, CollaRx aimed to provide a "drug delivery implant" that addressed the deficiencies in existing drug/device combination products. *Id.* at ¶ 78. CollaRx's application states that the collagen sponge must meet specific characteristics to ensure its effectiveness and safety, including "the collagen sponge's viscosity, the method of its sterilization, the method of its preparation by first immersing the sponge in a saline solution and then inserting

an acidic solution." *Id.* at ¶ 79. According to Plaintiffs, CollaRx's complexity makes clear that the FDA would require CollaRX to receive FDA approval as a device. *Id.* at ¶ 80.

4. Intercenter Agreement

Plaintiffs cite the 1991 Intercenter Agreement between the Center for Drug Evaluation and Research and Center for Devices and Radiological Health. The Intercenter Agreement is a guidance document accessible on the FDA's website. It is intended to guide the industry on which products will be regulated as devices or drugs and, pursuant to that distinction, the appropriate center in which to submit applications. Defendants argue that the Intercenter Agreement is merely a guidance document listing "nonbinding determinations"[3] that in no way suggests that XaraColl should have been tested and treated as a drug/device combination product. Namely, Defendants contend that because the examples enumerated in the agreement do not explicitly state whether they utilize collagen, such examples are distinguishable from XaraColl and, therefore, could not have put Defendants on adequate notice. As Plaintiffs point out, however, the Intercenter Agreement states that "a device with [the] primary purpose of delivering or aiding in the delivery of a drug and distributed containing a drug and distributed containing a drug (*i.e.*, 'prefilled delivery system')" is considered a *drug/device combination product*. Pl.s' Ex. 2 at 5 (Doc. No. 53-2). Moreover, the Intercenter Agreement explicitly lists injectable collagen as an example of a device. *Id.* at 9.

[3] Pursuant to 21 C.F.R. § 3.5(2), the "intercenter agreements, and any amendments thereto, are nonbinding determinations designed to provide useful guidance to the public."

5. FDA's Inactive Ingredients Database

Plaintiffs also cite the FDA's "inactive ingredients" database to suggest that Defendants should have known that collagen is not an excipient[4] because the database does not include collagen used to place an analgesia in a surgery location. Defendants counter that the inferences Plaintiffs urge upon the Court are inapposite because the database does not purport to address which ingredients may qualify as excipients.

C. Knowledge Required to Allege Recklessness

The parties vigorously dispute whether the second amended complaint adequately plead that Defendants knew, or should have known, to treat XaraColl as a drug/device combination product. First, Defendants argue that the second amended complaint alleges only that Mr. Zook had generalized knowledge of the XaraColl patent's language. They also argue that the second amended complaint fails to allege that Mr. Zook or Dr. Russell actually knew of or read the Intercenter Agreement or the FDA's "inactive ingredients" database.

To be sure, "'[g]eneralized imputations of knowledge do not suffice, regardless of the defendants' positions within the company.'" *In re Campbell Soup*, 145 F. Supp. 2d at 598 (quoting *In re Advanta*, 180 F.3d at 539).[5] However, "securities fraud claims typically have sufficed to state a claim based on recklessness when they have specifically alleged defendants' knowledge of facts *or access to information* contradicting their public statements. Under such circumstances,

[4] An excipient is defined as "[a]n inactive substance that serves as the vehicle or medium for a drug or other active substance." *Bracco Diagnostics, Inc. v. Maia Pharm., Inc.*, No. 17-13151, 2019 WL 4885888, at *2 n.1 (D.N.J. Oct. 3, 2019) (citing Oxford English Dictionary).

[5] Even so, "[k]nowledge concerning a company's key businesses or transactions may be attributable to the company, its officers and directors." *In re Tel-Save Sec. Litig.*, No. 98-3145, 1999 WL 999427, at *5 (E.D. Pa. Oct. 19, 1999) (citing *In re Aetna Inc. Sec. Litig.*, 34 F. Supp. 2d 935, 953 (E.D. Pa. 1999)); *In re Campbell Soup*, 145 F. Supp. 2d at 599).

defendants knew or, *more importantly, should have known* that they were misrepresenting material facts related to the corporation." *Id.* at 599 (quoting *Novak*, 216 F.3d at 308) (emphasis added).

Defendants' arguments ignore the fact that recklessness can be alleged based on the their mere "*access to information*" in contradiction to their public statements. *Id.* (quoting *Novak*, 216 F.3d at 308) (emphasis added). It is unnecessary to read in an additional requirement that Plaintiffs must explicitly plead that Defendants examined or considered the information available to them. As Defendants acknowledge, the information which Plaintiffs cite as indicative of the fact that Defendants should have known or clearly suspected XaraColl's status as a drug/device combination was all information that was accessible to Defendants. Even assuming Plaintiffs failed to allege *any* facts that Defendants reviewed the evidence at issue,[6] Plaintiffs have certainly alleged Defendants' easy *access* to such evidence.

In addition, Defendants contend that to adequately plead scienter under a recklessness theory, the alleged misleading statements or omissions *must* "directly contradict or ignore statements or issues that *had been specifically raised by the FDA*" to the wrongdoer. Def.s' Mem. in Supp. at 27 (Doc. No. 50-1) (emphasis in original). However, contrary to Defendants' argument, Plaintiffs are to identify "reports or statements that are contradictory to the statements made, or must provide specific instances in which Defendants received information that was contrary to their public declarations." *Glaser*, 772 F. Supp. 2d at 588. Although an affirmative warning from the FDA would be a notable example of information that could support an inference of recklessness, the Court does not adopt Defendants' argument that such warnings from the FDA are actually *required* to establish recklessness. In advancing this argument, Defendants, ironically, rely on a case, *In re Mannkind Sec. Actions*, 835 F. Supp. 2d 797 (C.D. Cal. 2011), in which

[6] With that being said, Plaintiffs' allegations about Mr. Zook's personal reliance on the XaraColl patent suggests an inference that, at the very least, Mr. Zook did read the patent's language.

Defendants uttered allegedly misleading statements *before* the FDA alerted them of the inadequacy of their methodology.[7] Moreover, Plaintiffs pointed out at oral argument here that the FDA never warned Defendants to treat XaraColl as a drug/device combination because Defendants never raised the issue to the FDA, a fundamental point of Plaintiffs' pleading. Oral Argument Tr. 21:5-12; *see infra* at 31-32.

Ultimately, Defendants' arguments ignore the fact that recklessness is *intended* to encompass "willful blindness.'" *Benjamin*, 1999 WL 249706, at *8; *see supra* at 15. Indeed, "allowing recklessness to serve as a sufficient basis for liability 'promotes the policy objective[] of discouraging deliberate ignorance[.]" *Avaya, Inc.*, 564 F.3d at 270 (quoting *In re Advanta*, 180 F.3d at 535). Defendants' contention that recklessness was not adequately pled because the FDA never explicitly warned them of the issue at hand cuts against this policy objective. Following the logic of defendants' argument, defendants would be motivated to hide potential concerns from the FDA, a proposition that flies in the face of the intended scope of the statutes and case law at hand. Suggesting that Plaintiffs failed to plead recklessness because Defendants possibly failed to review important information accessible to them equally runs afoul of the policy objective to discourage deliberate ignorance. Therefore, the Court rejects the argument that Plaintiffs' alleged evidence cannot be used to also allege recklessness.

D. Holistic Analysis of Scienter

As noted, the Court's scienter analysis ultimately turns on "'whether all of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation,

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[7] In *In re Mannkind*, the court denied the defendants' motion to dismiss. According to Innocoll's description, the defendants in *In re Mannkind* told investors that the FDA vetted their method of proving bioequivalency "when, in fact, the defendants had been specifically told by the FDA that the method was 'inadequate.'" Def.s' Mem. in Supp. at 27 (Doc. No. 50-1). As Plaintiffs point out, according to the reported opinion in the case, the FDA actually told the defendants in *In re MannKind* that their method was "inadequate" *after* they submitted their New Drug Application. *Id.* at 803, 908.

scrutinized in isolation, meets that standard.'" *Avaya, Inc.*, 564 F.3d at 267 (quoting *Tellabs*, 551 U.S. at 323). Hence, having considered the allegations one by one, the Court now considers the package. The parties set forth two competing narratives.

On the one hand, Plaintiffs theorize that FDA sources and Defendants' own patents should have put them on notice that Innocoll ought to, at the very least, inquire into whether XaraColl required additional device trials and approval. Despite having access to this information, Defendants, strapped for cash and eager to cut corners, decided to forgo spending the necessary $10 million for device trials altogether. According to Plaintiffs, Defendants refrained from disclosing their calculated risk for financial and personal reasons. Misleading positive statements omitting their risk could lead to higher stock valuation and prices, which in turn raises cash to fund their drug trials. Misstatements could also entice a prospective buyer, Gurnet Point, to offer more money for its potential acquiring of XaraColl. In fact, the latter could have resulted in Mr. Zook personally making a $5.5 million profit. Finally, Plaintiffs allege that Mr. Zook and Dr. Russell feared that disclosing the truth would jeopardize their careers.

On the other hand, Defendants assert that they simply made a very expensive and unintended mistake.[8] If Innocoll really was aware of XaraColl's device components or features,

[8] For the first time at oral argument, Defendants argued that the plain language of the PSLRA supports their understanding that submitting a New Drug Application for XaraColl was proper. Pursuant to 21 U.S.C. § 321(h), a "device" is (i) "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article;" (ii) "which does not achieve its primary intended purpose through chemical action" within the body; and (iii) "which is not dependent upon being metabolized for the achievement of its primary intended purpose." According to Defendants, this language—alongside their assertion that the Intercenter Agreement apparently provides no relevant guidance—renders it nearly impossible for the Court to conclude that Plaintiffs pleaded recklessness. As noted, language in the Intercenter Agreement could have provided valuable guidance to, at the very least, inquire into whether XaraColl required device testing. Moreover, the Court disagrees with Defendants' insistence that this language renders Defendants' alleged recklessness an absolute impossibility.

why, they ask, would Innocoll not test those components at the same time as the drug components?[9]

Indeed, Plaintiffs "did not quite" allege a cogent retort to Defendants' rhetorical question in their first amended complaint. Mem. at 11 (Doc. No. 46). After conducting a whole "package" analysis of Plaintiffs' bolstered second amended complaint, however, the Court finds that Plaintiffs have now pleaded sufficient particularized facts alleging a cogent inference of scienter that is at least as compelling as Defendants' competing narrative. Moreover, Defendants' arguments of what Plaintiffs must have alleged to support a strong inference of scienter goes against the guidance of the Supreme Court and the Third Circuit Court of Appeals.[10] *See supra* sections I.B-C*; see also Avaya, Inc.*, 564 F.3d at 267.

Therefore, the Court finds that the second amended complaint adequately alleges a strong inference of scienter as is required pursuant to the PSLRA's heightened pleading requirements.

II. Material Misleading Statements or Omissions

In addition to pleading scienter, Plaintiffs must also plead facts demonstrating that "the defendant made a materially false or misleading statement or omitted to state a material fact necessary to make a statement not misleading." *Cal. Pub. Emps.' Ret. Sys. v. Chubb Corp.*, 394 F.3d 126, 143 (3d Cir. 2004).

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[9] This rhetorical question is based on Defendants' assertion that Innocoll could have conducted the additional studies required for a device application "simultaneously with the drug studies, at low risk and reasonable cost." Def.s' Mem. in Supp. at 32 (Doc. No. 50-1). Notably, the apparent low risk and reasonable cost of the additional device trials are not alleged in the second amended complaint. Although the Court, in conducting this holistic analysis, is to weigh the plausible, nonculpable explanations for the defendant's conduct against the inferences favoring the plaintiff, *Avaya, Inc.*, 564 F.3d at 267, Rule 12(b)(6)'s gatekeeping function still applies, *see In re NutriSystem, Inc.*, 653 F. Supp. 2d at 566 n.2 (noting that in analyzing a motion to dismiss under the PSLRA, the Court must only examine the second amended complaint in its entirety, documents incorporated into the complaint by reference, or matters of which a court may take judicial notice).

[10] Defendants repeatedly argue that Plaintiffs' factual allegations, when assessed each on its own, do not allege a strong inference of scienter. Such an emphasis on the strength of *individual* factual allegations, however, is misplaced in a *holistic* analysis as discussed above.

A. Materiality

Defendants argue that their alleged misleading statements or omissions were not material. Information is material if it "would be important to a reasonable investor in making his or her investment decision." *In re Burlington*, 114 F.3d at 1425. "Generally, undisclosed information is considered material if there is a substantial likelihood that the disclosure would have been viewed by the reasonable investor as having significantly altered the total mix of information available to that investor." *Oran v. Stafford*, 226 F.3d 275, 282 (3d Cir. 2000) (internal quotation marks and citations omitted). In the Third Circuit, "when a stock is traded in an efficient market, the materiality of disclosed information may be measured post hoc by looking to the movement, in the period immediately following disclosure of the price of the firm's stock." *Oran*, 226 F.3d at 282. Because "the concept of materiality translates into information that alters the price of the firm's stock" when operating in an efficient market, information disclosed is immaterial if the disclosure had no effect on stock prices. *Id.* (citing *In re Burlington*, 114 F.3d at 1425).

Here, Defendants disclosed that it was filing the XaraColl application as a New Drug Application instead of a Pre-Market Approval Application for a medical device. According to Defendants, because Innocoll admitted that it filed a New Drug Application and because the evidence Plaintiffs rely on was accessible during the class period, the "truth" was available on the market. With these "truths" available in the marketplace, Defendants argue that their omissions were therefore immaterial.

Defendants' argument is known as the "truth on the market" defense. "The 'truth of the market' defense recognizes that a statement or omission is materially misleading only if the allegedly undisclosed facts have not already entered the market." *Winer Family Trust v. Queen*, No. 03-4318, 2004 WL 2203709, at *4 (E.D. P. Sept. 27, 2004), *aff'd sub nom*, 503 F.3d 319 (3d

Cir. 2007). Understandably, "[t]he truth-on-the-market defense is intensely fact-specific and is rarely an appropriate basis for dismissing a § 10(b) complaint for failure to plead materiality." *Ganino v. Citizens Utilities Co.*, 228 F.3d 154, 167 (2d Cir. 2000). "To prevail on a 'truth of the market' defense at th[e] [motion to dismiss] stage of the litigation . . . defendants must establish defense as a matter of law on the basis of the allegations of the [second amended complaint.]" *In re Res. Am. Sec. Litig.*, No. 98-5446, 2000 WL 1053861, at *5 (E.D. Pa. July 26, 2000).

As it must, the Court accepts all factual allegations as true and construes the second amended complaint in the light most favorable to Plaintiffs. Here, Plaintiffs plead that Innocoll stock traded in an efficient market. Sec. Am. Compl. at ¶ 250. Because Innocoll eventually disclosed the FDA's determination that XaraColl required drug/device trials and approval, the Court looks to the movement in the price of Innocoll's stock following its disclosure to determine if the information might be material. The day after Innocoll disclosed that XaraColl required approval as a drug/device combination, Innocoll's stock price dropped 61% from its previous trading day's close. *Id.* at ¶ 150. At the motion to dismiss stage, courts have rejected the truth on the market defense when drops in stock prices have created reasonable inferences of the materiality of information not previously available on the market. *See, e.g.*, *In re Res. Am.*, 2000 WL 1053861, at *5. When viewing the allegations of the second amended complaint in the light most favorable to Plaintiffs, the Court therefore must reject Defendants' truth on the market defense at this stage of the litigation.

B. Actionable Misleading Statements or Omissions

Defendants next argue that their alleged misleading statements or omissions are non-actionable. A Rule 10b-5 plaintiff must "establish that [a] defendant made a materially false or misleading statement or omitted to state a material fact necessary to make a statement not

misleading." *In re Burlington*, 114 F.3d at 1417. "To be actionable, a statement or omission must have been misleading at the time it was made; liability cannot be imposed on the basis of subsequent events." *In re NAHC, Inc. Sec. Litig.*, 306 F.3d 1314, 1330 (3d Cir. 2002) (citations omitted). "Some statements, although literally accurate, can become, through their context and manner of presentation, devices which mislead investors. For that reason, the disclosure required by the securities laws is measured not by literal truth but by the ability of the material to accurately inform rather than mislead prospective buyers." *In re Merck & Co., Inc. Sec., Der. & ERISA Litig.*, Nos. 05-1151, 05-2367, 2011 WL 3444199, at *9 (D.N.J. Aug. 8, 2011) (quoting *McMahan & Co. v. Wherehouse Entm't, Inc.*, 900 F.2d 576, 579 (2d Cir. 1990)). "Once a defendant makes an affirmative statement or characterization about its business, it puts that subject 'in play' and assumes a duty, under the securities laws, to speak truthfully about that subject." *Id.* (quoting *Shapiro v. UJB Fin. Corp.*, 964 F.2d 272, 282 (3d Cir.1992), *rehearing en banc denied,* July 7, 1992); *see also Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 45 (2011) (noting that "companies can control what they have to disclose under [§ 10(b) and Rule 10b-5(b)] by controlling what they say to the market"). Although a company need not voluntarily disclose its internal forecasts or projections, that disclosure may be attacked if it is made without a "reasonable basis." *In re Burlington*, 114 F.3d at 1427-28. In examining "optimistic projections of approval[,]" this Circuit has acknowledged that optimism in the face of awareness of a potential issue "does not necessarily mean their omissions are actionable." *In re Amarin Corp. PLC Sec. Litig.*, 689 F. App'x 124, 132 (3d Cir. 2017) (citations omitted).

Defendants argue that the following statements are not misleading because they are either literally true or non-actionable statements of expectation: (1) statements that the FDA agreed with Innocoll on the primary endpoint and single-dose approach for the Phase III trials, Sec. Am.

Compl. at ¶¶ 99, 105, 106, 110-112, 116-118, 124, 130-132; (2) statements concerning Defendants' expectations and goals for completing the XaraColl approval process, *id.* at ¶¶ 105, 124, 131, 133, 140, 144, 145; (3) statements that Innocoll shared "non-clinical" issues concerning XaraColl with the FDA, *id.* at ¶ 120; (4) statements that Innocoll expected to submit a New Drug Application at the beginning of the fourth quarter of 2016, *id.* at ¶¶ 116, 124, 126, 127, 130; (5) Dr. Russell's statement that she did not think there were any "gating factors" that would preclude the submission of a fourth-quarter New Drug Application, *id.* at ¶ 127; (6) the announcement of the submission of the New Drug Application, *id.* at ¶ 138; and (7) expressions of confidence that the application would be accepted and approved, *id.* at ¶¶ 140, 142, 144, 145.

Defendants inappropriately focus on the literal accuracy of the statements instead of whether the statements accurately informed rather than misled prospective buyers. Defendants posit that their otherwise allegedly truthful statements or optimistic expectations could never be deemed misleading unless "the company should have known that [XaraColl] would have to be filed as . . . a device application . . . but filed only as a drug application anyway." Oral Argument Tr. 14:15-20. Indeed, that is precisely what Plaintiffs are alleging. According to Plaintiffs, the statements and omissions at issue are either false or misleading because they could have led a reasonable investor to believe that there was nothing substantial left for Defendants to do that had not already been disclosed to the FDA before receiving approval.

The Third Circuit and other courts have recognized that "a reasonable investor understands that a "[c]ontinuous dialogue between the FDA and the proponent of a new drug is the essence of the product license application process.'" *In re Amarin*, 689 F. App'x at 132 (quoting *Tongue v. Sanofi*, 816 F.3d 199, 211 (2d Cir. 2016) (alteration in original). Expanding on this sentiment, "[t]hese sophisticated investors, well accustomed to the 'customs and practices of the relevant

industry,' would fully expect that Defendants and the FDA were engaged in a dialogue . . . about the sufficiency of various aspects of the clinical trials . . . ." *Tongue*, 816 F.3d at 211. Moreover, a reasonable investor "would have considered the statements [expressing optimism] 'in light of all [the] surrounding text, including hedges, disclaimers, and apparently conflicting information.'" *Id.* (quoting *Omnicare, Inc. v. Laborers Dist. Council Const. Ind. Pension Fund*, 575 U.S. 175, 190 (2015)).

Defendants concede that they never raised the subject of device testing in Innocoll's meetings with the FDA. Sec. Am. Compl. at ¶ 151; Def.s' Supplemental Mem. at 4 (Doc. No. 68). Even so, Defendants argue that a reasonable investor would know that the FDA approval process is a back-and-forth, give-and-take dialogue that in no way guarantees success. Plaintiffs counter that a sophisticated investor would reasonably expect Defendants to have *utilized* this continuous dialogue as an opportunity to inquire into their rudimentary hurdles to success. If Defendants knowingly or recklessly submitted their New Drug Application after never, at the very least, inquiring into the apparent obstacle of conducting necessary device trials, it follows that Defendants' updates and optimistic expectations that FDA approval was all but a guarantee could certainly have been uttered without a reasonable basis. As noted below, the generic cautionary language accompanying some of Defendants' statements also failed to disclose the potential risk that the FDA would reject XaraColl's application due to Innocoll's assumption that XaraColl was a drug.

Therefore, the Court finds that Plaintiffs alleged actionable material misstatements and omissions in support of their claims.

III. Application of the PSLRA's "Safe Harbor" Provision

Finally, Defendants argue that their allegedly forward-looking statements contained in the Amended Registration statement, the Annual Reports on the 20-F Form, the prospectuses, conference calls, and press releases are protected pursuant to the PSLRA's "Safe Harbor" provision. Sec. Am. Compl. at ¶¶ 100, 105, 116, 124, 127, 130, 131, 133, 140, 142, 144, 145. "[The] Safe Harbor provision immunizes from liability any forward-looking statement, provided that: the statement is identified as such and accompanied by meaningful cautionary language; or is immaterial; or the plaintiff fails to show the statement was made with actual knowledge of its falsehood." *Avaya, Inc.*, 564 F.3d at 254 (internal citations omitted); *In re Aetna, Inc. Sec. Litig.*, 617 F.3d 272, 278-89 (3d Cir. 2010).

Because the statements at issue are not accompanied by meaningful cautionary language, the PSLRA's "Safe Harbor" provision is inapplicable here.[11] "Cautionary language must be 'extensive and specific.'" *GSC Partners*, 368 F.3d at 243 n. 3 (quoting *Seremenko v. Cendant Corp.*, 223 F.3d 165, 182 (3d Cir. 2000)). "'[A] vague or blanket (boilerplate) disclaimer which merely warns the reader that the investment has risks will ordinarily be inadequate to prevent misinformation. To suffice, the cautionary statements must instead be substantive and tailored to the specific future projections, estimates or opinions in the prospectus which the plaintiffs challenge.'" *GSC Partners*, 368 F.3d at 243 n. 3 (quoting *In re Trump Casino Sec. Litig.*, 7 F.3d 357, 371-72 (3d Cir. 1993)). For example, in *Institutional Inv'rs Grp. v. Avaya, Inc.*, 564 F.3d 242 (3d Cir. 2009), the Third Circuit Court of Appeals determined that Defendants' cautionary language was adequate because they included a "detailed list of specific factors and uncertainties

[11] For purposes of assessing the application of the "Safe Harbor" provision, the Court need not address whether the statements at issue are forward-looking, material, or were made with actual knowledge of its falsehood.

that could affect its future economic performance," expressly warned that the forward looking statements might turn out to be wrong, warned of uncertainties in the marketing strategy, and highlighted competition from competitors. *Id.* at 257.

In evaluating the meaningfulness of cautionary language, courts have rejected the alleged significance of boilerplate warnings true to every company that interacts with the FDA. For example, in *Yanek v. Staar Surgical Co.*, 388 F. Supp. 2d 1110 (C.D. Cal. 2005), that court rejected applying the PSLRA's "Safe Harbor" provision to statements that could apply to "literally any issues subject to FDA regulation." *Id.* at 1123. The rejected cautionary language in that case, which is similar to the cautionary language used here, included statements that "[t]he FDA approval process is typically lengthy and expensive, and approval is never certain," and that "[n]oncompliance with applicable United States regulatory requirements can lead to . . . denial or withdrawal of pre-marketing approvals." *Id.* Moreover, courts have taken into consideration whether a company's cautionary language changes overtime to incorporate new information and risks. *See, e.g.*, *Gormley v. Magicjack Vocaltec Ltd.*, 220 F. Supp. 3d 510, 515 (S.D.N.Y. 2016) ("If the language has not changed over time to 'reflect new information and new risks,' the language 'may be boilerplate.'"); *In re Discovery Lab. Sec. Litig.*, No. 06-1820, 2006 WL 3227767, at *16 (E.D. Pa. Nov. 1, 2006) (finding cautionary language to be meaningful when "[t]he list of likely risks changed over time and from one press release to another").

Deeming their cautionary language used "far too extensive to quote or even cite in this brief[,]" Def.s' Mem. in Supp. at 36 (Doc. No. 50-1), Defendants rely on two main examples of their alleged meaningful cautionary language. First, they cite language found in their 2014 and 2015 registration statements and annual reports:

> Obtaining approval of a[] [New Drug Application] is a lengthy, expensive and uncertain process, and approval may not be obtained.

> If we submit a[] [New Drug Application] to the FDA, the FDA must decide whether to accept or reject the submission for filing. We cannot be certain that any of our submissions will be accepted for filing and review by the FDA, or if the FDA will approve the application if it accepts it.

Def.s' Ex. 1 at 21, 26 (Doc. No. 50-2); Def.s' Ex. 2 at 9, 13 (Doc. No. 50-3); Def.s' Ex. 4 at 13, 18 (Doc. No. 50-5). The June 2016 preliminary and final prospectus supplements and the May 2016 post-effective amendment also incorporated this language by reference. Def.s' Ex. 5 at cover page, S-13, S-46 (Doc. No. 50-6); Def.s' Ex. 6 at cover page, S-13, S-45 (Doc. No. 50-7); Def.s' Ex. 7 at (Doc. No. 50-8). Second, Defendants cite a press release stating that the allegedly forward-looking statements at issue:

> Involve substantial risks and uncertainties including, but not limited to, the risk that the FDA and foreign regulatory authorities may not agree with [Innocoll's] interpretation of the data from [its] clinical trials of XARACOLL and may require us to conduct additional clinical trials; XARACOLL may not receive regulatory approval or be successfully commercialized, including as a result of the FDA's or other regulatory authorities' decisions . . . .

Def.s' Ex. 8. at 6 (Doc. No. 50-9). The cited cautionary language is a far cry from the detailed disclosures at issue in *Avaya, Inc.* Defendants argue that they could not have possibly needed to disclose more than the risk that the FDA may not accept XaraColl's New Drug Application. Oral Argument Tr. 17:17-19. Such a generic warning, however, is inherently true of any and every New Drug Application. Plaintiffs contend that the cautionary language could have easily included language explaining that Innocoll assumed XaraColl to be a drug and, if that assumption was wrong, that the FDA may find the New Drug Application to be incomplete. *Id.* at 21:24-22:2. The Court agrees. In addition, it is telling that Innocoll did not develop its disclosures in an attempt to tailor its risks over time. Apart from the press release, the cautionary language cited by Defendants did not change from 2014 to 2016. Therefore, the Court finds that the PSLRA's "Safe Harbor" provision does not apply to any of Defendants' statements.

IV. Section 20(a) Claims

"Section 20(a) of the Exchange Act imposes joint and several liability upon one who controls a violator of Section 10(b)." *In re Suprema Specialties, Inc. Sec. Litig.*, 438 F.3d 256, 284 (3d Cir. 2006). "Accordingly, liability under Section 20(a) is derivative of an underlying violation of Section 10(b) by the controlled person." *Avaya, Corp.*, 564 F. 3d at 252. Because the Court finds that Plaintiffs' second amended complaint states a claim under Rule 10b-5, the Section 20(a) claims also survive Defendants' Rule 12(b)(6) motion. *See In re Viropharma Sec. Litig.*, 21 F. Supp. 3d 458, 470 (E.D. Pa. 2014) ("Because this Court finds that Plaintiff indeed does state a claim under Rule 10b-5, Plaintiff's Section 20(a) claim survives.").

CONCLUSION

For the reasons set forth in this Memorandum, the Court denies Defendants' motion to dismiss. An appropriate order follows.

BY THE COURT:

GENE E.K. PRATTER
UNITED STATES DISTRICT JUDGE